(j) Adequate samples of incoming raw materials are taken and appropriate analyses of these samples made;

(k) Preparation of manufacturing records and forms is done with such clarity, care and completeness so that each lot or batch of drugs manufactured, prepared, relabeled, or repacked is so identified that the complete manufacturing, packing, and labeling history and control examination reports are readily available and so as to eliminate mistakes and confusion;

(l) Each batch or lot of drugs manufactured, prepared, relabeled or repacked is properly identified at all times and during all stages of said manufacturing, preparation, relabeling or repacking;

(m) Operations involving the weighing out of raw materials and the preparation of formulas and application of labeling are checked by another qualified party in addition to the employee originally performing such duties;

(n) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion and the possibility of mistakes;

(o) Samples of each lot of raw materials and each batch or lot of drugs manufactured, prepared, relabeled or repacked by them are taken and retained for the time reasonably necessary for the distribution and use of drugs distributed;

(p) Representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare are given free access to all records and controls pertaining to (1) the receipt of all raw materials or lots of drugs for manufacturing, preparing, repacking or relabeling; (2) the manufacturing, preparing, repacking or relabeling of all lots or batches of drugs; and (3) the distribution of all batches or lots of drugs whether interstate or intrastate, including, but not limited to, the records necessary to establish that adequate control systems have been installed embodying all of the herein listed safeguards for interstate commerce considered necessary to good pharmaceutical manufacturing practice.

6488. Procaine penicillin G in streptomycin sulfate in aqueous suspension. (F.D.C. No. 44851. S. No. 34–825 R.)

QUANTITY: 2,942 vials at New York, N.Y.

SHIPPED: On 3–31–60, from New York, N.Y., to Phoenix, Ariz., and returned to New York on 6–9–60.

LABEL IN PART: "10 cc. size 5 doses Procaine Penicillin G in Streptomycin Sulfate in Aqueous Suspension."

RESULTS OF INVESTIGATION: Examination showed that the article was badly discolored and lumpy; that it could not with certainty be uniformly resuspended; that withdrawal with a 22-gauge needle was nearly impossible; and that the article contained substantially less than its labeled content of penicillin and streptomycin.

LIBELED: On or about 8–19–60, S. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from and its purity and quality fell below that which it purported and was represented to possess, since *procaine penicillin G in streptomycin sulfate in aqueous suspension* is recognized in the Antibiotic Regulations (21 CFR 146a.67) and it failed to conform to the standard set forth in such regulations since it did not contain the potency represented and it was not in an aqueous

suspension which, upon being shaken a reasonable length of time, would insure a uniform distribution of solid in vehicle and, therefore, uniform and proper dosage.

DISPOSITION: 9–20–60. Default—destruction.

6489. Sodium para-aminosalicylic acid tablets. (F.D.C. No. 43394. S. No. 61–104 P.)

QUANTITY: 74 24-btl. cartons and 25 btls. at Detroit, Mich.

SHIPPED: Between 5–22–59 and 6–4–59, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: "1,000 Tablets Salamin Sodium Each Tablet Contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)."

RESULTS OF INVESTIGATION: Examination showed that the article contained 87.6 percent of the labeled amount of sodium para-aminosalicylic acid; that the average weight of tablets in two subdivisions was below declared weight of active ingredient; and that a substantial number of broken tablets were found in the sample. United States Pharmacopeia requires *sodium para-aminosalicylic acid tablets* to contain from 95 to 105 percent of labeled amount of the drug.

LIBELED: 7–22–59, E. Dist. Mich.

CHARGE: 501(b)—when shipped, the article purported to be a drug recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below the standard set forth in the compendium; 502(a)—the label statement "Each tablet contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)" was false and misleading.

DISPOSITION: 12–28–60. Consent—claimed by shipper and reconditioned to be brought into compliance with the law.

6490. Posterior pituitary injection. (F.D.C. No. 45135. S. No. 41–134 R.)

QUANTITY: 12 vials at St. Louis, Mo.

SHIPPED: 8–22–60, from Chicago, Ill., by Medical Chemicals Corp.

LABEL IN PART: (Vial) "10 cc Sterile Multiple Dose Vial Posterior Pituitary Injection 10 U. S. P. Units/cc (Obstetrical) 0.5 Chlorobutanol * * * Medical Chem. Corp. Chicago 51, Ill. 6132."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was not more than 4.6. U. S. P. posterior pituitary units per cubic centimeter.

LIBELED: 11–7–60, E. Dist. Mo.

CHARGE: 501(b)—when shipped, the strength of the article fell below the standard set forth in the United States Pharmacopeia; and 502(a)—the label statement "Posterior Pituitary Injection 10 U. S. P. Units/cc" was false and misleading.

DISPOSITION: 12–14–60. Default—destruction.

6491. Rubber prophylactics. (F.D.C. No. 44536. S. No. 32–793/5 R.)

QUANTITY: 56 ctns., each containing 48 3-unit paper sleeves; 138 ctns., each containing 48 3-unit plastic cans; 198 ctns., each containing 12 paper sleeves of 4 3-unit paper packs, at Brooklyn, N.Y.

SHIPPED: 2–16–60 and 3–18–60, from Akron, Ohio, by March Rubber & Plastic Co.